1637

DOCKET NO. CDS-219

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ortho-Clinical Diagnostics, Inc.

Serial No.: 10/019,514 Art Unit: 1637

Filed: February 21,2003 Examiner: Kim, Young J

For: RAPID **AND EFFICIENT CAPTURE OF DNA FROM SAMPLE WITHOUT USING CELL LYSING REAGENT**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Missing Parts, Assistant Commissioner for Patents, Washington, DC 20231 on

May 12, 2005

(Date of Deposit)

Catherine Kurtz Gowen

(Name of applicant, assignee, or Registered Representative)

/Catherine Kurtz Gowen/

(Signature)

May 12, 2005

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This paper is submitted in response to the Office Action dated 04/28/2005 for which the one (1) month date for response is 05/28/2005.

RESTRICTION REQUIREMENT

Claims 1-22 are pending in this application and are subject to restriction and/or election requirement. The Office Action states the application contains the following inventions or groups of inventions which are not linked so as to form a single general inventive concept under PCT Rule 13.1, and that in accordance with Rule 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, drawn to a method of extracting nucleic acid from a sample.

Group II, claims 7-22, drawn to a method of amplifying nucleic acid sample, an embodiment drawn to the amplification of K-ras sequence and primers/oligonucleotides involved in the amplification reaction. This group is subject to further restriction.

The Examiner further avers the inventions listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims drawn to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

(1) A product and a process of producing the product
(2) A product and a process of using the product
(3) A product, process of producing the product, and a process of using the product
(4) A process and an apparatus of means to carry out the process
(5) A product, a process of producing the product, and an apparatus of means to carry out the process.

The Examiner avers that Group II reads on distinct Groups drawn to multiple sequences, which are distinct because they are unrelated sequences and lack of unity is applied to each group, thus the Applicants must further elect two SEQ IS NOS (pairs of primers) for examination in the elected Group detailed above, and that specifically the SEQ ID NOS elected for claim 10 must be the same for claims 11-22, and that claims resulting in

becoming drawn to non-elected SEQ IS NOS as a result of Applicants' election with be withdrawn from further consideration as being drawn to non-elected invention.

Applicants elect, with traverse, Group I, claims 1-6, drawn to a method of extracting nucleic acid from a sample.

PCT Rule 13.2 outlines the criteria for what is considered unity of invention:

Unity of invention is present only when there is a "technical relationship" among the claimed inventions involving one or more of the same or corresponding "special technical features." The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The determination whether a group of inventions is so linked as to form a single inventive concept is made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.
An initial determination of unity of invention based on the assumption that the claims avoid the prior art will be made before the prior art search but may be reconsidered on the basis of the results of the search. Annex B of the Administrative Instructions contains detailed criteria governing the determination whether an international application complies with the requirement of unity of invention under Rule 13. The following paragraphs set out a summary of some of the more important criteria discussed in that Annex. Illustrations of three particular situations are explained in detail below:

(i) combinations of different categories of claims (for example—product, process, use, and apparatus or means),
(ii) so-called "Markush practice," and
(iii) the case of intermediate and final products.

Applicants submit that claims 1-6 and 7-9 fulfill the above requirement of there being a "technical relationship" among the claimed inventions involving one or more of the same or corresponding "special technical features." It is Applicants' position that claims 1-9 are all directed to obtaining a nucleic acid from a sample without use of a lysing agent.

In view of the foregoing, Applicants respectfully request that claims 1-9 should be examined together.

Respectfully submitted,

/Catherine Kurtz Gowen/
Catherine Kurtz Gowen
Registration No. 32,148
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
(732) 524-2681
DATE: May 12, 2005